10/585221

STEPPED BALLOON CATHETER FOR TREATING VASCULAR BIFURCATIONS

IAP20 Rec'd PCT/PTO 30 JUN 2006

CROSS-REFERENCES TO RELATED APPLICATIONS

This application is a Continuation-In-Part of U.S. Patent Application Serial No. 11/190,514 filed on July 27, 2005 which is a Continuation-in-Part of U.S. Patent Application Serial No. 11/076,448 filed on March 9, 2005, which is a Continuation-in-Part of co-pending U.S. Patent Application Serial No. 10/807,643 filed on March 23, 2004, which claims the benefit of priority of U.S. Provisional Application No. 60/463,075, filed on April 14, 2003, the full disclosures of which are incorporated in their entireties herein by reference. This application also claims the benefit of priority of U.S. Patent Application Serial No. 10/965,230, filed on October 13, 2004, and the full disclosure of which is incorporated by reference in its entirety herein.

Background of the Invention

Field of the Invention

Embodiments of the present invention relate generally to medical devices and methods. More particularly, embodiments of the present invention relate to the structure and deployment of a prosthesis having a stent or other support structure and at least one, and in some implementations at least two fronds for deployment at a branching point in the vasculature or elsewhere.

Maintaining the patency of body lumens is of interest in the treatment of a variety of diseases. Of particular interest to the present invention are the transluminal approaches to the treatment of body lumens. More particularly, the percutaneous treatment of atherosclerotic disease involving the coronary and peripheral arterial systems. Currently, percutaneous coronary interventions (PCI) often involve a combination of balloon dilation of a coronary stenosis (i.e. a narrowing or blockage of the artery) followed by the placement of an endovascular prosthesis commonly referred to as a stent.

A major limitation of PCI/stent procedures is restenosis, i.e., the re-narrowing of a blockage after successful intervention typically occurring in the initial three to six months post treatment. The recent introduction of drug eluting stents (DES) has dramatically reduced the incidence of restenosis in coronary vascular applications and offers promise in peripheral stents, venous grafts, arterial and prosthetic grafts, as well as A-V fistulae. In

deployment, it is difficult and frequently not possible to re-enter the side branch after crush stenting. Unproven long-term results coupled with concern regarding the inability to re-enter the side branch, malaposition of the stents against the arterial wall and the impact of three layers of stent (which may be drug eluting) opposed against the main vessel wall has limited the adoption of this approach.

These limitations have led to the development of stents specifically designed to treat bifurcated lesions. One approach employs a stent design with a side opening for the branch vessel which is mounted on a specialized balloon delivery system. The specialized balloon delivery system accommodates wires for both the main and side branch vessels. The system is tracked over both wires which provides a means to axially and radially align the stent/stent delivery system. The specialized main vessel stent is then deployed and the stent delivery system removed while maintaining wire position in both the main and side branch vessels. The side branch is then addressed using the kissing balloon technique or by delivering an additional stent to the side branch. Though this approach has many theoretical advantages, it is limited by difficulties in tracking the delivery system over two wires (*See, e.g.*, United States Patent Nos. 6,325,826 and 6,210,429 to Vardi et al.).

Notwithstanding the foregoing efforts, there remains a need for improved devices as well as systems and methods for delivering devices, to treat body lumens at or near the location of an Os between a main body lumen and a side branch lumen, typically in the vasculature, and more particularly in the arterial vasculature. It would be further desirable if such systems and methods could achieve both sufficient radial support as well as adequate surface area coverage in the region of the Os and that the prostheses in the side branches be well-anchored at or near the Os.

<u>Description of the Related Art</u>

Stent structures intended for treating bifurcated lesions are described in U.S. Patent Nos. 6,599,316; 6,596,020; 6,325,826; and 6,210,429. Other stents and prostheses of interest are described in the following U.S. Patent Nos.: 4,994,071; 5,102,417; 5,342,387; 5,507,769; 5,575,817; 5,607,444; 5,609,627; 5,613,980; 5,669,924; 5,669,932; 5,720,735; 5,741,325; 5,749,825; 5,755,734; 5,755,735; 5,824,052; 5,827,320; 5,855,598; 5,860,998; 5,868,777; 5,893,887; 5,897,588; 5,906,640; 5,906,641; 5,967,971; 6,017,363; 6,033,434; 6,033,435; 6,048,361; 6,051,020; 6,056,775; 6,090,133; 6,096,073; 6,099,497; 6,099,560; 6,129,738; 6,165,195; 6,221,080; 6,221,098; 6,254,593; 6,258,116; 6,264,682; 6,346,089;

coating, and may be configured to exhibit at least one of a controlled drug release rate, a constant release rate, bi-modal drug release rate, or a controlled concentration of drug proximate a target vessel wall.

There is provided in accordance with one aspect of the present invention, a prosthesis and deployment system assembly. The assembly comprises an elongate flexible catheter body, having a balloon thereon. The balloon has an inflated profile with a first section having a first diameter, a second section having a second diameter, and a balloon transition in-between the first and second sections. A prosthesis is carried by the balloon. The prosthesis has a wall, having a first wall pattern adjacent the first section of the balloon, and a second wall pattern adjacent the balloon transition. In one embodiment, the prosthesis has a third wall pattern adjacent the second section of the balloon.

There is provided in accordance with another aspect of the present invention, a prosthesis and deployment catheter system for treating an opening from a main body lumen to a branch body lumen. The prosthesis comprises a radially expansible support, the support configured to be deployed in at least a portion of the branch body lumen. A plurality of fronds extends axially from an end of the support, and are configured to be positioned across the Os and into the main body lumen. At least one circumferential link connects at least a first and a second frond, the circumferential link spaced axially apart from the support.

The prosthesis is mounted on a balloon catheter, such that the radially expansible support is carried by a first portion of a balloon that is inflatable to a first diameter, and the circumferential link is carried by a second portion of a balloon that is inflatable to a second diameter, that is larger than the first diameter.

The circumferential link may connect each of the plurality of fronds. Preferably, the plurality of fronds includes at least three fronds. Each frond may comprise a resilient metal.

At least a portion of the resiliently expansible support may comprise a drug coating, and at least a portion of the fronds and the circumferential link are without a drug coating. The drug coating may be a drug eluting coating, and may be configured to produce at least one of a controlled drug delivery rate, a constant drug delivery rate, bimodal drug release rate, or a controlled concentration of drug proximate a target vessel wall. The drug may be configured to reduce an incidence or amount of restenosis.

Fig. 1A is a detailed view of the fronds of the prosthesis of Fig. 1, shown with the fronds deployed in broken line.

Fig. 2-is a cross-sectional view taken along line 2-2 of Fig. 1.

Figs. 2A-2E are lateral views showing embodiments of a stent having fronds in a rolled out configuration. Fig. 2A shows an embodiment having serpentine-shaped fronds, Fig. 2B shows an embodiment having filament shaped fronds, while Fig. 2C shows an embodiment having filament shaped fronds with alternating shortened fronds. Figures 2D and 2E illustrate a nested transition zone configuration with two different stent wall patterns.

Fig. 2F is a lateral view as in Fig. 2D, with the added feature of a circumferential link to assist in maintaining the spacial orientation of the fronds.

Figs. 3A and 3B are lateral and cross sectional views illustrating an embodiment of a stent having fronds and an underlying deployment balloon having a fold configuration such that the balloon folds protrude through the spaces between the fronds.

Figs. 4A and 4B are lateral and cross sectional views illustrating the embodiment of Figs 3A and 3B with the balloon folded over to capture the fronds.

Figs. 5A-5C are lateral views illustrating the deployment of stent fronds using an underlying deployment balloon and a retaining cuff positioned over the proximal portion of the balloon. Fig. 5A shows pre-deployment, the balloon un-inflated; Fig 5B shows deployment, with the balloon inflated; and Fig 5C post-deployment, the balloon now deflated.

Figs. 6A-6B are lateral views illustrating the change in shape of the cuff during deployment of a stent with fronds. Fig 6A shows the balloon in an unexpanded state; and Fig 6B shows the balloon in an expanded state, with the cuff expanded radially and shrunken axially.

Figs. 6C-6D are lateral views illustrating an embodiment of a cuff configured to evert upon balloon inflation to release the fronds.

Figs. 7A-7B are lateral views illustrating an embodiment of a tether for restraining the stent fronds.

Figs. 8A-8B are lateral views illustrating an embodiment of a proximally retractable sleeve for restraining the stent fronds.

Fig. 24 is a side elevational view as in Fig. 23, with a modified catheter in accordance with the present invention.

Fig. 24A is a cross sectional view taken along the line 24A-24A of Fig. 24.

Fig. 24B is a cross sectional view taken along the line 24B-24B in Fig. 24.

Fig. 25 is a schematic view of a two guidewire catheter in accordance with the present invention, in position at a vascular bifurcation.

Fig. 26 is a schematic representation as in Fig. 25, showing the second guidewire advanced distally through the fronds.

Fig. 27 is a schematic view as in Fig. 25, with a modified two guidewire catheter in accordance with the present invention.

Detailed Description of the Preferred Embodiment

Embodiments of the present invention provide improved prostheses and delivery systems for their placement within a body lumen, particularly within a bifurcated body lumen and more particularly at an Os opening from a main body lumen to a branch body lumen. The prostheses and delivery systems will be principally useful in the vasculature, most typically the arterial vasculature, including the coronary, carotid and peripheral vasculature; vascular grafts including arterial, venous, and prosthetic grafts such as a bifurcated abdominal aortic aneurysm graft, and A-V fistulae. In addition to vascular applications, embodiments of the present invention can also be configured to be used in the treatment of other body lumens including those in the gastrointestinal systems (e.g., esophagus, large and small intestines, biliary system and pancreatic ducts) and the genital-urinary system (e.g., ureter, urethra, fallopian tubes, vas deferens), and the like.

The prosthesis in accordance with the present invention generally comprises three basic components: a stent or other support, at least one frond extending from the support, and a transition zone between the support and the frond. These components may be integrally formed such as by molding, or by laser or other cutting from tubular stock, or may be separately formed and secured together.

The term "fronds" as used herein will refer to any of a variety of structures including anchors, filaments, petals or other independently multiaxially deflectable elements extending from the stent or other support structure, to engage an adjacent main vessel stent or other associated structure. These fronds can expandably conform to and at least partially circumscribe the wall of the main body vessel to selectively and stably

Deformation of the fronds to conform to at least a portion of the wall of the main body lumen provides a generally continuous coverage of the Os from the side branch lumen to the main vessel lumen. Further and/or complete expansion of the fronds within the main body lumen may press the fronds firmly against the main body lumen wall and open up the fronds so that they do not obstruct flow through the main body lumen, while maintaining patency and coverage of the side branch and os.

Usually, the prosthesis will include at least two or three fronds extending axially from the end of the support. The prosthesis could include four, five, or even a greater number of fronds, but the use of three such fronds is presently contemplated for a coronary artery embodiment. The fronds will have an initial length (i.e., prior to radial expansion of the prosthesis) which is at least about 1.5 times the width of the prosthesis prior to expansion, typically at least about 2 times the width, more typically at least about 5 times the width, and often about 7 times the width or greater. The lengths will typically be at least about 2 mm, preferably at least about 3 mm, and more preferably at least about 6 mm. The frond length may also be considered relative to the diameter of the corresponding main vessel. For example, a prosthesis configured for use in a branch vessel from a main vessel having a 3 mm lumen will preferably have a frond length of at least about 7 mm and in some embodiments at least about 9 mm.

Embodiments of the present invention incorporating only a single frond are also contemplated. The single frond may extend axially from the branch vessel support as has been described in connection with multi frond embodiments. Alternatively, the single frond (or two or three or more fronds) may extend in a helical or spiral pattern, such that it wraps in a helical winding about the longitudinal axis extending through the branch vessel support.

The fronds may have a fixed width or a width which is expandable to accommodate the expansion of the support, and the fronds may be "hinged" at their point of connection to the support to permit freedom to adapt to the geometry of the main vessel lumen as the prosthesis is expanded. As used herein, "hinged" does not refer to a specific structure such as a conventional hinge, but rather to any combination of structures, materials and dimensions that permit multiaxial flexibility of the frond relative to the support so that the frond can bend in any direction and/or rotate about any axis to conform to the ablumenal surface of the expanded main vessel stent under normal use conditions. It is also possible

detached from the fronds prior to expansion of the expandable member. In alternative embodiments, the tether can be configured to break or release upon expansion of the expandable member so as to release the fronds.

In an exemplary deployment protocol using the prosthesis delivery system, the delivery catheter is advanced to position the prosthesis at a target location in a body lumen. During advancement, at least a portion of the fronds are radially constrained to prevent divarication of the fronds from the delivery catheter. When the target location is reached, the radial constraint is released and the prosthesis is deployed within the lumen.

In various embodiments, the release of the fronds and expansion of the prosthesis can occur simultaneously or alternatively, the radial constraint can be released prior to, during, or after expanding/deploying the prosthesis. In embodiments where the radial constraint comprises balloon folds covering the fronds or a cuff or tether, the constraint can be released as the balloon is inflated. In alternative embodiments using a cuff or tether, the cuff/tether can be withdrawn from the fronds prior to expansion of the support.

Embodiments of the above protocol can be used to deploy the prosthesis across the Os of a branch body lumen and trailing into the main body lumen. In such applications, the prosthesis can be positioned so that the stent lies within the branch body and at least two fronds extend into the main body lumen. The fronds are then circumferentially deformed to conform to at least a portion of the main vessel wall to define a main vessel passage through the fronds. At least two and preferably at least three fronds extend into the main body lumen.

Radiopaque or other medical imaging visible markers can be placed on the prostheses and/or delivery balloon at desired locations. In particular, it may be desirable to provide radiopaque markers at or near the location on the prosthesis where the stent is joined to the fronds. Such markers will allow a transition region of the prosthesis between the stent and the fronds to be properly located near the Os prior to stent expansion. The radiopaque or other markers for locating the transition region on the prosthesis can also be positioned at a corresponding location on a balloon catheter or other delivery catheter. Accordingly, in one embodiment of the deployment protocol, positioning the prosthesis can include aligning a visible marker on at least one of the prosthesis, on the radial constraint, and the delivery balloon with the Os.

Referring now to Figs. 1 and 2, an embodiment of a prosthesis and delivery system 5 of the present invention for the delivery of a prosthesis to a bifurcated vessel can include a prosthesis 10 and a delivery catheter 30. Prosthesis 10 can include at least a radially expansible support section 12 and a frond section 14 with one or more fronds 16. The base of the fronds resides in a transition zone, described below. In various embodiments, the frond section 14 includes at least two axially extending fronds 16, with three being illustrated.

Balloon catheters suitable for use with the prosthesis of the present invention are well understood in the art, and will not be described in great detail herein. In general, a catheter suitable for use for deployment of the prosthesis of the present invention will comprise an elongate tubular body extending between a proximal end and a distal end. The length of the (catheter) tubular body depends upon the desired application. For example, lengths in the area of from about 120 cm to about 140 cm are typical for use in a percutaneous transluminal coronary application intended for accessing the coronary arteries via the femoral artery. Other anatomic spaces including renal, iliac, femoral and other peripheral applications may call for a different catheter shaft length and balloon dimensions, depending upon the vascular access site as will be apparent to those of skill in the art.

The catheter shaft is provided with at least one central lumen, for an inflation media for inflating an inflatable balloon carried by the distal end of the catheter shaft. In an over the wire embodiment, the catheter shaft is additionally provided with a guidewire lumen extending throughout the entire length thereof. Alternatively, the prosthesis of the present invention may be deployed from a rapid exchange or monorail system, in which a proximal access port for the guidewire lumen is provided along the side wall of the catheter shaft distally of the proximal manifold, such as within about the distal most 20 cm of the length of the balloon catheter, or from a convertible system as is known in the art.

The catheter shaft for most applications will be provided with an approximately circular cross sectional configuration, having an external diameter within the range of from about 0.025 inches to about 0.065 inches depending upon, among other things, whether the target bifurcation is in the coronary or peripheral vasculature. Systems may have diameters in excess of about 0.25 inches and up to as much as about 0.35 inches in certain applications. Diameters of from about 1.5 mm up to as large as about 7 mm are

but often comprises at least two axially extending elements 66A and 66D, and optimally three or more axially extending elements, which can be spaced laterally apart from each other upon radial expansion of the prosthesis, to increase in width in the circumferential direction. The increased width referred to herein will differ on a given frond depending upon where along the length of the frond the measurement is taken. Fronds of the type illustrated herein will increase in width the most at the end attached to the support, and the least (or none) at the free apex end as will be appreciated by those of skill in the art. Circumferentially expanding at least the base of the frond enables optimal wall coverage in the vicinity of the ostium, following deployment of the prosthesis at the treatment site. In addition, multiple elements results in a greater surface area as a biological substrate or increased delivery of pharma agents.

In the illustrated embodiments, each of the fronds 16 has an equal width with the other fronds 16. However, a first frond or set of fronds may be provided with a first width (measured in a circumferential direction) and a second frond or set of fronds may be provided with a second, different width. Dissimilar width fronds may be provided, such as alternating fronds having a first width with fronds having a second width.

In each of the foregoing constructions, radially symmetry may exist such that the rotational orientation of the prosthesis upon deployment is unimportant. This can simplify the deployment procedure for the prosthesis. Alternatively, prostheses of the present invention exhibiting radial asymmetry may be provided, depending upon the desired clinical performance. For example, a first frond or set of fronds may be centered around 0° while a second frond or set of fronds is centered around 180° when the prosthesis is viewed in a proximal end elevational view. This may be useful if the fronds are intended to extend around first and second opposing sides of the main vessel stent. Asymmetry in the length of the fronds may also be accomplished, such as by providing fronds at a 0° location with a first length, and fronds at 180° location with a second length. As will become apparent below, such as by reference to Figure 9A, certain fronds in the deployed prosthesis will extend along an arc which aligns with the axis of the branch vessel at a distal end, and aligns with the axis of the main vessel at a proximal end. The proximal ends of fronds of equal length will be positioned axially apart along the main vessel lumen. If it is desired that the proximal ends of any of the fronds align within the same transverse cross section

described above, in alternate constructions, the fronds may have a width that remains constant or substantially constant throughout the length of the frond as the prosthesis is deployed.

The fronds may be "hinged" as has been described at their point of connection to the support to permit freedom to adapt to the geometry of the main vessel lumen as the prosthesis is expanded. It is also possible that each frond is attached at a single point to the support, thus reducing the need for such expandability at the junction between the frond and the support. The fronds may be congruent, i.e., have identical geometries and dimensions, or may have different geometries and/or dimensions. Again, further description of the fronds may be found in co-pending Application Serial No 10/807,643.

Fronds 16, will usually extend axially from the support section 12, as illustrated, but in some circumstances the fronds can be configured to extend helically, spirally, in a serpentine pattern, or other configurations as long as the configuration permits placement of the stent in a vessel such that the fronds extend across the Os. It is desirable, however, that the individual fronds be radially separable so that they can be independently, displaced, folded, bent, rotated about their longitudinal axes, and otherwise positioned within the main body lumen after the support section 12 has been expanded within the branch body lumen. In the schematic embodiment of Fig. 1, the fronds 16 may be independently folded out in a "petal-like" configuration, forming petals 16p, as generally shown in broken line for one of the fronds in Figs. 1 and 2.

In preferred embodiments, fronds 16 will be attached to the support section 12 such that they can both bend and rotate relative to an axis A thereof, as shown in broken line in Fig. 1A. Bending can occur radially outwardly and rotation or twisting can occur about the axis A or a parallel to the axis A as the fronds are bent outwardly. Such freedom of motion can be provided by single point attachment joints as well as two point attachments or three or more point attachments.

Referring now to Fig. 2A, an exemplary embodiment of a prosthesis 50 (shown in a "rolled out" pattern) comprises a support or stent section 52 and a frond section 54. Support section 52 comprises a first plurality of radially expansible serpentine elements 56 which extend circumferentially to form a cylindrical ring having a plurality of open areas or cells 57 therein. The cylindrical rings formed by serpentine elements 56 are coaxially aligned along the longitudinal axis of the support section 52, and, in the illustrated

conditions which will result in different final geometries for the fronds in use. The final configuration of the fronds in the main vessel lumen will depend on a number of factors, including length of the fronds and geometry of the vasculature and will vary greatly from deployment to deployment. While the fronds together will cover at least a portion of the main vessel wall circumference, most fronds will also be deformed to cover an axial length component of the main vessel wall as well. Such coverage is schematically illustrated in the figures discussed below.

In other embodiments, prosthesis structure 50 can include four or five or six or more fronds 16. Increasing the number of fronds provides an increased number of anchor points between a branch vessel stent and a main vessel stent. This may serve to increase the mechanical linkage between stent 10 and another stent deployed in an adjacent vessel. In various embodiments, fronds 16 can be narrower (in width) than embodiments having few fronds so as to increase the flexibility of the fronds. The increased flexibility can facilitate the bending of the fronds during stent deployment including bending from the branch body lumen into the main body lumen.

Referring now to Fig. 2B, in various embodiments, fronds 16 can comprise thin filaments formed into loops 17. An exemplary embodiment of a prosthesis structure 50 having a plurality of filament loops 17 is shown in FIG 2B in a rolled out pattern. In various embodiments filament loops 17 can have at least one or two or more intra-filament connectors 18, 19 which extend in a circumferential direction to connect two adjacent filaments defining a filament loop 17. Connectors 18, 19 preferably include at least one nonlinear undulation such as a "U", "V" or "W" or "S" shape to permit radial expansion of the prosthesis in the vicinity of the fronds. (The intra-filament space may be crossed with a balloon catheter and dilated to larger diameters).

The illustrated embodiment includes a first intra-filament connector 18 in the transition area 60 for each frond 16, and a second connector 19 positioned proximally from the first connector 18. One or both of the first and second connectors 18, 19 can be configured to expand or otherwise assume a different shape when the fronds are deployed. At least five or ten or 20 or more connectors 18, 19 may be provided between any two adjacent filaments 66 depending upon the desired clinical performance. Also connectors 18, 19 can be continuous with frond loops 17 and have substantially the same cross sectional thickness and/or mechanical properties. Alternatively, connectors 18, 19 can have

proliferative, anti-inflammatory and/or anti-cell migration drugs such as Taxol (paclitaxel), Rapamycin and their derivatives, the use of high filament type fronds serve as a means to reduce the incidence and rate of hyperplasia and restenosis. Similar results can be obtained with other drugs known in the art for reducing restenosis (e.g. anti-neo-plastics, anti-inflammatory drugs, etc.). Also in a related embodiment the filament fronds can be coated with a different drug and/or a different concentration of drug as the remainder of the stent. In use, such embodiment can be configured to provide one or more of the following: i) a more constant release rate of drug; ii) bimodal release of drug; iii) multi drug therapies; and iv) titration of drug delivery/concentration for specific vessels and/or release rates. As disclosed in additional detail below, the drug may be incorporated into a biostable, biodegradeable, or bioerodable polymer matrix, and may be optimized for long-term pharma release (prophylactic local drug delivery).

In general, in any of the embodiments herein, the prosthesis of the present invention can be adapted to release an agent for prophylactic or active treatment from all or from portions of its surface. The active agents (therapy drug or gene) carried by the prosthesis may include any of a variety of compounds or biological materials which provide the desired therapy or desired modification of the local biological environment. Depending upon the clinical objective in a given implementation of the invention, the active agent may include immunosuppressant compounds, anti-thrombogenic agents, anti-cancer agents, hormones, or other anti-stenosis drugs. Suitable immunosuppressants may include ciclosporinA (CsA), FK506, DSG(15-deoxyspergualin, 15-dos), MMF, rapamycin and its derivatives, CCI-779, FR 900520, FR 900523, NK86-1086, daclizumab, depsidomycin, kanglemycin-C, spergualin, prodigiosin25-c, cammunomicin, demethomycin, tetranactln, tranilast, stevastelins, myriocin, gllooxin, FR 651814, SDZ214-104, bredinin, WS9482, and steroids. Suitable anti-thrombogenic drugs may include anti-platelet agents (GP IIb/IIIa, thienopyridine, GPIb-IX, ASA, etc and inhibitors for the coagulation cascade (heparin, hyrudin, thrombin inhibitors, Xa inhibitors, VIIa Inhibitors, Tissue Factor Inhibitors and the like) Suitable anti-cancer (anti proliferative) agents may include methotrexate, purine, pyridine, and botanical (e.g. paclitaxel, colchicines and triptolide), epothilone, antibiotics, and antibodies. Suitable additional anti-stenosis agents include batimastat, NO donor, 2-chlorodeoxyadenosine, 2-deoxycoformycin, FTY720, Myfortic, ISA (TX) 247, AGI-1096, OKT3, Medimmune, ATG, Zenapax, Simulect, DAB486-IL-2, Anti-ICAM-1,

polymers; starch; collagen; hyaluronic acid; gelatin; lactone-based polyesters or copolyesters, e.g. polylactide; polyglycolide; polylactide-glycolide; polycaprolactone; polycaprolactone-glycolide; poly(hydroxybutyrate); poly(hydroxyvalerate); polyhydroxy (butyrate-co-valerate); polyglycolide-co-trimethylene carbonate; poly(diaxanone); polyorthoesters; polyanhydrides; polyaminoacids; polysaccharides; polyphospoeters; polyphosphoester-uretha- ne; polycyanoacrylates; polyphosphazenes; poly(ether-ester) copolymers, e.g. PEO-PLLA, fibrin; fibrinogen; or mixtures thereof; and biocompatible non-degrading materials, e.g. polyurethane; polyolefins; polyesters; polyamides; polycaprolactame; polyimide; polyvinyl chloride; polyvinyl methyl ether; polyvinyl alcohol or vinyl alcohol/olefin copolymers, e.g. vinyl alcohol/ethylene copolymers; polyacrylonitrile; polystyrene copolymers of vinyl monomers with olefins, e.g. styrene acrylonitrile copolymers, ethylene methyl methacrylate copolymers; polydimethylsiloxane; poly(ethylene-vinylacetate); acrylate based polymers or coplymers, e.g. polybutylmethacrylate, poly(hydroxyethyl methylmethacrylate); polyvinyl pyrrolidinone; fluorinated polymers such as polytetrafluoethylene; cellulose esters e.g. cellulose acetate, cellulose nitrate or cellulose propionate; or mixtures thereof.

When a polymeric matrix is used, it may comprise multiple layers, e.g. a base layer in which the drug(s) is/are incorporated, e.g. ethylene-co-vinylacetate and polybutylmethacrylate, and a top coat, e.g. polybutylmethacrylate, which is drug(s)-free and acts as a diffusion-control of the drug(s). Alternatively, the active agent may be comprised in the base layer and the active co-agent may be incorporated in the outlayer, or vice versa. Total thickness of the polymeric matrix may be from about 1 to 20 μ or greater.

The drug(s) elutes from the polymeric material or the stent over time and enters the surrounding tissue, e.g. up to ca. 1 month to 10 years. The local delivery according to the present invention allows for high concentration of the drug(s) at the disease site with low concentration of circulating compound. The amount of drug(s) used for local delivery applications will vary depending on the compounds used, the condition to be treated and the desired effect. For purposes of the invention, a therapeutically effective amount will be administered; for example, the drug delivery device or system is configured to release the active agent and/or the active co-agent at a rate of 0.001 to 200 μ g/day. By therapeutically effective amount is intended an amount sufficient to inhibit cellular proliferation and resulting in the prevention and treatment of the disease state. Specifically, for the

the stent surface. Stents including both a heparin surface and an active agent stored inside of a coating are disclosed, for example, in U.S. Pat. Nos. 6,231,600 and 5,288,711.

A variety of agents specifically identified as inhibiting smooth muscle-cell proliferation, and thus inhibit restenosis, have also been proposed for release from endovascular stents. As examples, U.S. Pat. No. 6,159,488 describes the use of a quinazolinone derivative; U.S. Pat. No. 6,171,609, describes the use of taxol, and U.S. Pat. No. 5,176,98, the use of paclitaxel, a cytotoxic agent thought to be the active ingredient in the agent taxol. The metal silver is cited in U.S. Pat. No. 5,873,904. Tranilast, a membrane stabilizing agent thought to have anti-inflammatory properties is disclosed in U.S. Pat. No. 5,733,327.

More recently, rapamycin, an immunosuppressant reported to suppress both smooth muscle cell and endothelial cell growth, has been shown to have improved effectiveness against restenosis, when delivered from a stent. See, for example, U.S. Pat. Nos. 5,288,711 and 6,153,252. Also, in PCT Publication No. WO 97/35575, the monocyclic triene immunosuppressive compound everolimus and related compounds have been proposed for treating restenosis, via systemic delivery.

Use of multiple filaments per frond also provides for a more open structure of the fronds section 54 of the prosthesis to allow for an easier and less obstructed passage of a guide wire and/or the deployment balloon by and/or through the fronds (e.g., during un-jailing procedures known in the art). Similarly, use of the flexible filaments also allows the main vessel to track between fronds and engage the main vessel stent. In particular, the thinner frond filaments facilitate advancement of the fronds over the circumference and/or the length of a main vessel stent during deployment of the fronds or the main vessel stent. Moreover, the filaments can be configured to be easily withdrawn and then re-advanced again to allow for repositioning of either of the branch vessel stent. Other means for facilitating advancement of the main vessel stent between the fronds can include tapering the fronds and/or coating the fronds with a lubricous coating such as PTFE or silicone (this also facilitates release of the fronds from constraining means described herein). Finally, by having an increased number of filaments, the mechanical support of the Os is not compromised if one or more filaments should become pushed aside during the stent deployment. That is, the remaining filaments provide sufficient support of the Os to maintain it patency. In these and related embodiments, it may be desirable to have at least

In each of the embodiments of Figures 2D and 2E, the struts 70 at the frond root (e.g. transition zone) are provided with an interdigitating or nesting configuration. In this configuration, as viewed in the flat, laid out view as in Figures 2D and 2E, a plurality of struts 70 extend across the transition zone. A distal segment 72 of each strut 70 inclines laterally in a first direction, to an apex 74, and then inclines laterally in a second direction to a point that may be approximately axially aligned with a distal limit of the distal segment 72. The extent of lateral displacement of the strut between its origin and the apex 74 is greater than the distance between adjacent struts, when in the unexpanded configuration. In this manner, adjacent struts stack up or nest within each other, each having a concavity 78 facing in a first lateral direction and a corresponding convexity 80 in a second lateral direction. This configuration seeks to optimize vessel wall coverage at the ostium, when the stent is expanded.

The axial length of each frond is at least about 10%, often at least about 20%, and in some embodiments at least about 35% or 75% or more of the length of the overall prosthesis. Within this length, adjacent fronds may be constructed without any lateral interconnection, to optimize the independent flexibility. The axially extending component of the frond may be provided with an undulating or serpentine structure 82, which helps enable the fronds to rotate out of the plane when the main vessel stent is deployed. Circumferential portions of the undulating fronds structure make the frond very flexible out of the plane of the frond for trackability. A plurality of connectors 84 are provided between parallel undulating filaments 86, 88 of each frond, to keep the frond from being overly floppy and prone to undesirable deformation. Each of the fronds in the illustrated embodiment has a broad (i.e. relatively large radius) frond tip 90, to provide an atraumatic tip to minimize the risk of perforating the arterial or other vascular wall.

The interdigitating construction in the transition zone, as well as the undulating pattern of the frond sections both provides optimal coverage at the ostium, and provides additional strut length extension or elongation capabilities, which may be desirable during the implantation process.

It may also be desirable to vary the physical properties of the filaments, 86, 88, or elsewhere in the prosthesis, to achieve desired expansion results. For example, referring to Figure 2E, each frond 16 includes a first filament 92, attached at a first attachment point 94 and a second filament 96 attached at a second attachment point 98 to the stent. A third

distal end of the transition zone and a second radiopaque marker at the proximal end of the transition zone. The proximal and distal radiopaque markers may take the form of radiopaque bands of material, or discreet markers which are attached to the prosthesis structure. This will enable centering of the transition zone on a desired anatomical target, relative to the ostium of the bifurcation. In general, it is desirable to avoid positioning the stent or other support such that it extends into the main vessel. A single marker may be used to denote the placement location of the transition zone.

Alternatively, the marker band or bands or other markers may be carried by the deployment catheter beneath the prosthesis, and axially aligned with, for example, the proximal and distal ends of the transition zone in addition to markers delineating the proximal and distal end of the prosthesis

Although the prosthesis has been disclosed herein primarily in the context of a distal branch vessel stent carrying a plurality of proximally extending fronds, other configurations may be constructed within the scope of the present invention. For example, the orientations may be reversed such that the fronds extend in a distal direction from the support structure. Alternatively, a support structure such as a stent may be provided at each of the proximal and distal ends of a plurality of frond like connectors. This structure may be deployed, for example, with a distal stent in the branch lumen, a plurality of connectors extending across the ostium into the main vessel, and the proximal stent deployed in the main vessel proximal to the ostium. A separate main vessel stent may thereafter be positioned through the proximal stent of the prosthesis, across the ostium and into the main vessel on the distal side of the bifurcation.

In addition, the prosthesis has been primarily described herein as a unitary structure, such as might be produced by laser cutting the prosthesis from a tubular stock. Alternatively, the prosthesis may be constructed such as by welding, brazing, or other attachment techniques to secure a plurality of fronds onto a separately constructed support. This permits the use of dissimilar materials, having a variety of hybrid characteristics, such as a self expandable plurality of fronds connected to a balloon expandable support. Once released from a restraint on the deployment catheter, self expandable fronds will tend to bias radially outwardly against the vascular wall, which may be desirable during the process of implanting the main vessel stent. Alternatively, the entire structure can be self expandable or balloon expandable, or the support can be self expandable as is described

link. Although it may add to the wall thickness, the circumferential link may be interlocked with or crimped to the fronds.

The circumferential link may alternatively be a polymeric band or tubular sleeve. For example, a radially expandable tubular sleeve may be positioned around the outside surface of the fronds, or adjacent the lumenal surface of the fronds. A polymeric circumferential link may also be formed such as by dipping the fronds or spraying the fronds with a suitable polymeric precursor or molten material. Polymeric circumferential links may be permanent, severable, or may be bioabsorbable or bioerodeable over time.

One embodiment of a circumferential link is illustrated schematically in Figure 2F. In this embodiment, a circumferential link 120 is provided, which connects each adjacent pair of fronds together, to produce a circumferential link 120 which extends completely around the axis of the prosthesis. In this illustration, the circumferential link 120 thus comprises a discrete transverse connection between each adjacent pair of fronds. Thus, for example, a first segment 122 is provided between a first and a second frond. The first segment 122 is expandable or enlargeable in a circumferential direction. A first segment 122 has a first end 126 at the point of attachment of the first segment 122 to a first frond, and a second end 128 at a point of attachment between the first segment 122 and a second frond. The arc distance or the linear distance between the first end 126 and second end 128 measured in a plane transverse to the longitudinal axis of the prosthesis is enlargeable from a first distance for transluminal navigation, to a second distance following expansion of the fronds within the main vessel. To accommodate the radial expansion of the circumferential link 120, the first segment 122 is provided with an undulating configuration having at least one and optionally 2 or three or more apex 130, as will be understood in the art. In one embodiment, each adjacent pair of fronds is connected by a transverse segment (e.g., 122, 124 etc.) and each of the transverse segments is identical to each other transverse segments.

Although the first segment 122 and second segment 124 are each illustrated in Figure 2F as comprising only a single transversely extending filament, two or three or more filaments may be provided between each adjacent pair of fronds, depending upon the desired performance. As used herein, the term "circumferential link" does not limit the link 120 to only a single filament between adjacent fronds. For example, the circumferential link may comprise a stent or other support structure which is similar to the support structure 52.

exposed to ambient atmospheric pressure. Any of a variety of thin walled flexible tubing may be utilized, such as a thin walled latex tubing, such that the inside diameter of the latex tubing may be approximately 10% less than the nominal expanded diameter of the stent. The stent is expanded within the tubing, such as by inflating an associated dilation balloon to its rated burst pressure or other pressure sufficient to expand the stent to its intended implanted diameter. The balloon may be deflated and the balloon catheter withdrawn. The tubing is mounted in the pressure chamber as described above. Air or other inflation media may be pumped into the pressure chamber to slowly increase the pressure within the chamber (for example at a rate of about 1 psi per second). Once any portion of the central lumen through the prosthesis has been reduced under pressure to less than or equal to 50% of its original lumen diameter, the pressure in the chamber is noted and considered to be the radial force or crush resistance of the prosthesis.

The second radially expandable structure (circumferential link) may also have a shorter axial length than the first radially expandable structure (stent). For example, in a coronary artery embodiment, the axial length of the stent may be at least 300% or 500% or more of the length of the circumferential link.

The fronds will have a length in the axial direction between the support 52 and the circumferential link 120 of generally in excess of about 2.5 mm or 3mm, and in certain embodiments in excess of about 5mm. At least some or all of the fronds may have a length in excess of about 8 mm, and, in one implementation of the invention intended for the coronary artery, the frond length is in the vicinity of about 9.4 mm.

The circumferential link may also have a smaller strut profile compared to the strut profile in the support 52. For example, the cross sectional dimensions of a strut in the support 52 and/or the fronds may be on the order of about 0.003 inches by about 0.055 inches in an embodiment intended for coronary artery applications. In the same embodiment, the cross sectional dimensions through a strut in the circumferential link may be on the order of about 0.001 inches by about 0.003 inches.

The frond length may also be evaluated relative to the main lumen diameter. For example, in the coronary artery environment, diameters in the range of from about 2 mm to about 5 mm are often encountered. Frond lengths of at least about equal to the main vessel diameter (e.g. at least about 2 mm or 3 mm or 4 mm or greater) are contemplated. Fronds

the stent through the vasculature or other body lumen. As shown in Figs 3A-3B, fronds 220 can be separated by axial gaps or splits 230 along the length of the frond structure. Splits 230 can have a variety of widths and in various embodiments, can have a width between 0.05 to 2 times the width of the fronds, with specific embodiments of no more than about 0.05, 0.25, 0.5, 1 and 2 times the width of the fronds. Fronds 220 can be configured to have sufficient flexibility to be advanced while in a captured mode through curved and/or tortuous vessels to reach the more distal portions of the vasculature such as distal portion of the coronary vasculature. This can be achieved through the selection of dimensions and/or material properties (e.g. flexural properties) of the fronds. For example, all or a portion of fronds 220 can comprise a resilient metal (e.g., stainless steel) or a superelastic material known in the art. Examples of suitable superelastic materials include various nickel titanium alloys known in the art such as Nitinol™.

Any of a variety of modifications or features may be provided on the fronds, to enhance flexibility or rotatability in one or more planes. For example, fronds may be provided with a reduced thickness throughout their length, compared to the thickness of the corresponding stent. The thickness of the frond may be tapered from relatively thicker at the distal (attachment) end to the proximal free end. Fronds may be provided with one or more grooves or recesses, or a plurality of wells or apertures, to affect flexibility. The specific configuration of any such flexibility modifying characteristic can be optimized through routine experimentation by those of skill in the art in view of the present disclosure, taking into account the desired clinical performance.

It is desirable to have the fronds captured and held against the delivery catheter or otherwise restrained as the stent is advanced through the vasculature in order to prevent the fronds from divaricating or separating from the prosthesis delivery system prosthesis. Capture of the fronds and prevention of divarication can be achieved through a variety of means. For example, in various embodiments the capture means can be configured to prevent divarication by imparting sufficient hoop strength to the fronds, or a structure including the fronds, to prevent the fronds from separating and branching from the deployment balloon as the balloon catheter is advanced through the vasculature including tortuous vasculature. In theses embodiments, the capture means is also configured to allow the fronds to have sufficient flexibility to be advanced through the vasculature as described above.

proximal portion of the stent and thus overly and capture the fronds. When the balloon is inflated, the overlying section of balloon material unfolds, releasing the fronds. The everted section of balloon can over all or any selected portion of the fronds. Eversion can be facilitated through the use of preformed folds described herein, in the case, the folds having a circumferential configuration. The folded section of balloon can be held in place by a friction fit or through the use of releasable low-strength heat bond or adhesive known in the art for bonding the balloon to the fronds. In one embodiment for positioning the everted section, the balloon is positioned inside the scaffold section of the stent and then partially inflated to have an end of the balloon protrude outside of the scaffold section, then the balloon is partially deflated and everted section is rolled over the fronds and then the balloon is fully deflated to create a vacuum or shrink fit of the balloon onto the fronds.

In various embodiments, fronds 210 can be captured by use of a tubular cuff 250 extending from the proximal end 241p of delivery balloon 241 as is shown in Figs. 5A-5C. In one embodiment, the cuff is attached to the catheter at or proximal to the proximal end 241p of the delivery balloon. In alternative embodiments, the cuff can be attached to a more proximal section of the catheter shaft such that there is an exposed section of catheter shaft between balloon and the cuff attachment point with the attachment point selected to facilitate catheter flexibility. Alternatively, the cuff is axially movably carried by the catheter shaft, such as by attachment to a pull wire which extends axially along the outside of or through a pull wire lumen within the catheter shaft, or to a tubular sleeve concentrically carried over the catheter shaft. In either approach, the cuff is positionable during translumenal navigation such that it overlies at least a portion of the fronds 220.

After prosthesis 210 is positioned at the target vascular site, the stent region is deployed using the delivery balloon as described herein. The frond(s) can be released by withdrawal of the restraint. In most embodiments, the entire catheter assembly including the cuff or other restraint, balloon, and catheter shaft are withdrawn proximally to fully release the fronds. In alternative embodiment the cuff can be slidably withdrawn while maintaining position of the delivery balloon. This embodiment permits frond release prior to or after stent deployment.

Release of the fronds by the cuff can be achieved through a variety of means. In one embodiment, cuff 250 can be configured such that the proximal frond tips 220t, slip out from the cuff when the balloon is deployed. Alternatively, the cuff may be scored or

release the enveloped fronds as is shown in Figs. 6C-6D. This can be facilitated by use of fold lines 252 described herein, as well as coupled the cuff to the balloon catheter. In one embodiment the cuff can be coaxially disposed over the proximal or distal end of the balloon catheter or even slightly in front of either end. This allows the cuff to disengage the fronds yet remain attached to the balloon catheter for easy removal from the vessel. In use, these and related embodiments allow the fronds to be held against the balloon to be radially constrained or captured during stent advancement and then easily released before, during or after balloon inflation to deploy the stent at the target site.

In various embodiments, all or a portion of cuff 250 can be fabricated from, silicones, polyurethanes (e.g., PEPAX) and other medical elastomers known in the art; polyethylenes; fluoropolymers; polyolefin; as well as other medical polymers known in the art. Cuff 250 can also be made of heat shrink tubing known in the art such as polyolefin and PTFE heat shrink tubing. These materials can be selected to produce a desired amount of plastic deformation for a selected stress (e.g. hoop stress from the inflation of deployment balloon). In particular embodiments, all or a portion of the materials comprising cuff 250 can be selected to have an elastic limit lower than forces exerted by inflation of the deployment balloon (e.g., the force exerted by 3 mm diameter balloon inflated to 10 atms). Combinations of materials may be employed such that different portions of the cuff (e.g., the proximal and distal sections or the inner and outer surfaces) have differing mechanical properties including, but not limited to, durometer, stiffness and coefficient of friction. For example, in one embodiment the distal portion of the cuff can high a higher durometer or stiffness than a proximal portion of the cuff. This can be achieved by constructing the proximal portion of the cuff from a first material (e.g., a first elastomer) and the distal portion out of a second material (e.g. a second elastomer). Embodiments of the cuff having a stiffer distal portion facilitate maintaining the fronds in a restrained state prior to deployment. In another embodiment, at least a portion of an interior surface of the cuff can include a lubricous material. Examples of suitable lubricious materials include fluoropolymers such as PTFE. In a related embodiment, a portion of the interior of the cuff, e.g., a distal portion, can be lined with lubricous material such as a fluoropolymer. Use of lubricous materials on the interior of the cuff aids in the fronds sliding out from under the cuff during balloon expansion.

Referring now to Figs. 9A-11B, an exemplary deployment protocol for using delivery system 5 to deliver a prosthesis (10) having a stent region (12) and having one or more fronds (16) will be described. The order of acts in this protocol is exemplary and other orders and/or acts may be used. A delivery balloon catheter 30 is advanced within the vasculature to carry prosthesis 10 having and stent region (12) and fronds 16 to an Os O located between a main vessel lumen MVL and a branch vessel lumen BVL in the vasculature, as shown in Figs. 9A and 9B. Balloon catheter 30 may be introduced over a single guidewire GW which passes from the main vessel lumen MVL through the Os O into the branch vessel BVL. Optionally, a second guidewire (not shown) which passes by the Os O in the main vessel lumen MVL may also be employed. Usually, the prosthesis 10 will include at least one radiopaque marker 20 on prosthesis 10 located near the transition region between the prosthesis section 12 and the fronds 16. In these embodiments, the radiopaque marker 20 can be aligned with the Os O, typically under fluoroscopic imaging.

Preferably, at least one proximal marker will be provided on the prosthesis at a proximal end of the transition zone, and at least one distal marker will be provided on the prosthesis at the distal end of the transition zone. Two or three or more markers may be provided within the transverse plane extending through each of the proximal and distal ends of the transition zone. This facilitates fluoroscopic visualization of the position of the transition zone with respect to the Os. Preferably, the transition zone is at least about 1 mm and may be at least about 2 mm in axial length, to accommodate different clinical skill levels and other procedural variations. Typically, the transition zone will have an axial length of no more than about 4 mm or 5 mm (for coronary artery applications).

During advancement, the fronds are radially constrained by a constraining means 250c described herein (e.g., a cuff) to prevent divarication of the fronds from the delivery catheter. When the target location is reached at Os O or other selected location, the constraining means 250c is released by the expansion of balloon 32 or other constraint release means described herein (alternatively, the constraining means can be released prior to balloon expansion). Balloon 32 is then further expanded to expand and implant the support region 12 within the branch vessel lumen BVL, as shown in Figs. 10A and 10B. Expansion of the balloon 32 also partially deploys the fronds 16, as shown in Figs. 10A and 10B, typically extending both circumferentially and axially into the main vessel lumen MVL. The fronds 16, however, are not necessarily fully deployed and may remain at least

the second balloon catheter 130, a second GW will usually be prepositioned in the main vessel lumen MVL past the Os O, as shown in Figs. 11A and 11B. Further details of various protocols for deploying a prosthesis having a stent region (12) and fronds or anchors, such as prosthesis 10, are described in co-pending Application Serial No. 10/807,643.

In various embodiments for methods of the invention using prosthesis/delivery system 5, the physician can also make use of additional markers 22 and 24 positioned at the proximal and distal ends of the prosthesis 10. In one embodiment, one or more markers 22 are positioned at the proximal ends of the fronds as is shown in Figs. 9A and 9B. In this and related embodiments, the physician can utilize the markers to ascertain the axial position of the stent as well as the degree of deployment of the fronds (e.g., whether they are in captured, un-captured or deployed state). For example, in one embodiment of the deployment protocol, the physician could ascertain proper axial positioning of the stent by not only aligning the transition marker 20 with the Os opening O, but also look at the relative position of end markers 22 in the main vessel lumen MVL to establish that the fronds are positioned far enough into the main vessel, have not been inadvertently positioned into another branch vessel/lumen. In this way, markers 20 and 22 provide the physician with a more accurate indication of proper stent positioning in a target location in a bifurcated vessel or lumen.

In another embodiment of a deployment protocol utilizing markers 22, the physician could determine the constraint state of the fronds (e.g. capture or un-captured), by looking at the position of the markers relative to balloon 30 and/or the distance between opposing fronds. In this way, markers 22 can be used to allow the physician to evaluate whether the fronds were properly released from the constraining means prior to their deployment. In a related embodiment the physician could determine the degree of deployment of the fronds by looking at (e.g., visual estimation or using Quantitative Coronary Angiography (QCA)) the transverse distance between markers 22 on opposing fronds using one or medical imaging methods known in the art (e.g., fluoroscopy). If one or more fronds are not deployed to their proper extent, the physician could deploy them further by repositioning (if necessary) and re-expanding balloon catheters 30 or 130.

Referring now to Fig. 12A-12I, an exemplary and embodiment of a deployment protocol using a deployment system 5 having a prosthesis 10 with fronds 16 will now be

The prosthesis of the present invention, may be utilized in combination with either main vessel stents having a substantially uniform wall pattern throughout, or with main vessel stents which are provided with a wall pattern adapted to facilitate side branch entry by a guidewire, to enable opening the flow path between the main vessel and the branch vessel. Three examples of suitable customized stent designs are illustrated in Figure 13A through 13C. In each of these constructions, a main vessel stent 110 contains a side wall 112 which includes one or more windows or ports 114. Upon radial expansion of the stent 110, the port 114 facilitates crossing of a guide wire into the branch lumen through the side wall 112 of the main vessel stent 110. A plurality of ports 114 may be provided along a circumferential band of the main vessel stent 110, in which instance the rotational orientation of the main vessel stent 110 is unimportant. Alternatively, as illustrated, a single window or port 114 may be provided on the side wall 112. In this instance, the deployment catheter and radiopaque markers should be configured to permit visualization of the rotational orientation of the main vessel stent 110, such that the port 114 may be aligned with the branch vessel.

In general, the port 114 comprises a window or potential window through the side wall which, when the main vessel stent 110 is expanded, will provide a larger window than the average window size throughout the rest of the stent 110. This is accomplished, for example, in Figure 13A, by providing a first strut 116 and a second strut 118 which have a longer axial distance between interconnection than other struts in the stent 110. In addition, struts 116 and 118 are contoured to provide a first and second concavity facing each other, to provide the port 114.

Referring to Figure 13B, the first strut 116 and second strut 118 extend substantially in parallel with the longitudinal axis of the stent 110. The length of the struts 116 and 118 is at least 2 times, and, as illustrated, is approximately 3 times the length of other struts in the stent. Referring to Figure 13C, the first and second struts 116 and 118 are provided with facing concavities as in Figure 13A, but which are compressed in an axial direction. Each of the foregoing configurations, upon expansion of the main vessel stent 110, provide an opening through which crossing of a guidewire may be enhanced. The prosthesis of the present invention may be provided in kits, which include a prosthesis mounted on a balloon catheter as well as a corresponding main vessel stent mounted on a balloon catheter, wherein the particular prosthesis and main vessel stent are configured to provide a working

implementation of the invention, the proximal zone 160 has an inflated diameter of about 3.5 mm and the distal zone 162 has an inflated diameter of about 2.5 mm. In general, the inflated diameter of the proximal zone 160 will be at least 110% of the inflated diameter of the distal zone 162. In certain implementations of the invention, the inflated diameter of the proximal zone 160 will be at least 125% of the inflated diameter of the distal zone 162.

The proximal zone 160 has a working length defined as the axial length between a proximal shoulder 166 and a distal shoulder 168. The working length of the proximal zone 160 is generally within the range of from about 5 to about 30mm, and, in one embodiment, is about 9mm. The working length of the distal zone 162 extends from a proximal shoulder 170 to a distal shoulder 172. The working length of the distal zone 162 is generally within the range of from about 5 to about 20mm, and, in one embodiment, is about 6mm. In the illustrated embodiment, each of the proximal zone 160 and distal zone 162 has a substantially cylindrical inflated profile. However, noncylindrical configurations may also be utilized, depending upon the desired clinical result.

The configuration and axial length of the transition zone 164 may be varied considerably, depending upon the desired frond configuration and ostium coverage characteristics of the implanted prosthesis. In the illustrated embodiment, the transition zone 164 comprises a generally frustoconical configuration, having an axial length between proximal shoulder 170 of the distal zone 162 and distal shoulder 168 of the proximal zone 160 within the range of from about 1 to about 10mm, and, in one embodiment, about 2.5mm.

The transition zone of this balloon delineates the transition from one diameter to another. In one embodiment this transition zone may be 4mm in length and ramp from 2.5 to 3.5mm in diameter. This conical surface is used to mold or flare the ostium of the bifurcation from the smaller side branch to the larger main vessel. In this configuration this stepped balloon may be utilized for deploying the prosthesis. Used in this manner the leading and trailing surfaces are utilized to expand the device in the side branch and main vessel and the transition zone is used to flare the transition zone of the stent against the wall of the ostium.

The wall of the stepped balloon 154 may comprise any of a variety of conventional materials known in the angioplasty balloon arts, such as any of a variety of nylons, polyethylene terephthalate, various densities of polyethylene, and others known in the art.

sequentially, depending upon the desired clinical procedure. Alternatively, a proximal balloon *160′* and a distal balloon *162′* may be both inflated by a single, common inflation lumen extending throughout the length of the catheter shaft.

The stepped balloon 154 is preferably navigated and positioned within the vascular system under conventional fluoroscopic visualization. For this purpose, the catheter 150 may be provided with at least one radiopaque marker. In the illustrated embodiment, a first radiopaque marker 174 is provided on the catheter shaft 152, at about the proximal shoulder 166. At least a second radiopaque marker 176 is provided on the shaft 152, aligned approximately with the distal shoulder 172. Proximal marker 174 and distal marker 176 allow visualization of the overall length and position of the stepped balloon 154.

In addition, a first transition marker 178 and second transition marker 180 may be provided on the shaft 152, at a location corresponding to a transition zone on the prosthesis. Transition markers 178 and 180 thus enable the precise location of the prosthesis transition with respect to the ostium between the main vessel and branch vessel, as has been discussed elsewhere herein. Each of the markers may comprise a band of gold, silver or other radiopaque marker materials known in the catheter arts.

In one embodiment of the stepped balloon 154 intended for use in the coronary artery, the axial length of the balloon between the proximal marker 174 and distal marker 176 is approximately 19.5 mm. The length between the distal marker 176 and transition marker 180 is approximately 6.1 mm. The distance between the transition markers 178 and 180, including the length of the transition markers, is about 4.5 mm. As will be apparent to those of skill in the art other dimensions may be utilized, depending upon the dimensions of the prosthesis and the target anatomy.

Referring to Figures 17 and 18, there is schematically illustrated two different configurations of a stepped balloon 154 in accordance with the present invention, positioned and inflated within a treatment site at a vascular bifurcation, with the prosthesis omitted for clarity. In each, a stepped balloon 154 is positioned such that a proximal zone 160 is inflated within a main vessel 182. A distal zone 162, having a smaller inflated diameter than proximal zone 160, is positioned within the branch vessel 184. The stepped balloon 154 has been positioned to illustrate the relative location of the transition markers 178 and 180, with respect to the carina 186 of the bifurcation.

The catheter 220 includes a guidewire lumen 228 which extends throughout the length of at least a distal portion of the catheter 220, to a distal port 230 at the distal end 224 of the catheter 220. In an embodiment intended for over-the-wire functionality, the first guidewire lumen 228 extends proximally throughout the length of the catheter, to a proximal manifold. In an alternate configuration intended for rapid exchange functionality, a proximal access port (not shown) provides access to the first guidewire lumen 228 at a point along the length of the catheter distal to the proximal end 222. In general, rapid exchange proximal access ports may be within the range of from about 10 cm to about 30 cm from the distal end 224.

As can be seen with reference to, for example, Fig. 23A, the catheter 220 is additionally provided with an inflation lumen 232 which extends throughout the length of the catheter to the proximal end 222. The distal end of inflation lumen 232 is in communication via an inflation port 234 with the interior of the balloon 226, to enable placement of the balloon 226 in fluid communication with a source of inflation media.

Referring to Fig. 23B, the catheter 220 is additionally provided with a second guidewire lumen 236. Second guidewire lumen 236 extends between a proximal access port 238 and a distal access port 240. The distal access port 240 is positioned proximally to the distal end 224 of the catheter 220. In the illustrated embodiment, the distal port 240 is positioned on the proximal side of the balloon 226. Generally, the distal port 240 will be no greater than about 4 cm, and often no greater than about 2 cm proximal of the balloon 226.

The proximal access port 238 may be provided on the side wall of the catheter, such as within the range of from about 10 cm to about 60 cm from the distal end 224. In one embodiment, the proximal access port 238 is within the range of from about 25 cm to about 35 cm from the distal end 224. The proximal port 238 is preferably spaced distally apart from the proximal end 222 of the catheter 220, to enable catheter exchange while leaving the main vessel guidewire in place as will be apparent in view of the disclosure herein.

As illustrated in Fig. 23, the second guidewire lumen 236 may be formed as an integral part of the catheter body. This may be accomplished by providing an initial 3 lumen extrusion having the desired length, and trimming away the wall of the second guidewire lumen 236 distally of the distal port 240 and proximally of the proximal port 238.

Referring to Fig. 27, there is illustrated an embodiment similar to Fig. 25, except that the distal exit port 240 of the main vessel guidewire lumen 236 is positioned proximally of the balloon. The precise location of the distal exit 240 may be varied, so long as it permits direction of the main vessel guidewire distally within the main vessel beyond the bifurcation. In general, the distal exit 240 may be located within the axial length of the prosthesis as mounted on the catheter.

Following distal advance of the main vessel guidewire 204 into the main vessel distally of the bifurcation, the catheter 208 may be proximally withdrawn from the treatment site leaving the main vessel guidewire 204 in place. The catheter 208 may be removed from the main vessel guidewire 204 as is understood in the rapid exchange catheter practices, and a secondary catheter may be advanced down the main vessel guidewire such as to dilate an opening between the fronds into the main vessel beyond the bifurcation and/or deploy a second stent at the bifurcation as has been discussed herein.

In Figs. 25 through 27, the catheter 208 is schematically illustrated as a construct of a separate main vessel lumen attached to a catheter body. However, in any of the foregoing catheters the body construction may be that of a unitary extrusion as has been discussed previously.

The stepped balloon of the present invention may be used in a variety of additional applications. For example, the distal lower diameter section of the device may be used to slightly open a small blood vessel then the system advanced to treat the index lesion with an appropriately sized catheter. In one embodiment the stepped balloon may function as a standard PTCA catheter for the treatment of advanced cardiovascular disease. Specifically in cases where only a small diameter balloon catheter is capable of crossing a diseased lesion, the smaller diameter leading portion of the step balloon may be used to predilate the lesion. The catheter would then be deflated and the larger diameter trailing segment advanced across the lesion. The larger diameter portion of the stepped balloon would then be used to dilate the diseased lesion to a larger diameter. In this way the stepped balloon functions as both a pre-dilation and final dilation catheter.

Although the present invention has been described primarily in the context of a prosthesis adapted for positioning across the Os between a branch vessel and a main vessel prior to the introduction of the main vessel stent, in certain applications it may be desirable to introduce the main vessel stent first. Alternatively, where the prosthesis of the present